## REMARKS/ARGUMENTS

Initially, the Examiner has restricted the application to one of two inventions. The first invention (Group I) is restricted to Claims 1-12 and 25, drawn to a composition comprising an aliphatic alcohol having from 1 to 4 carbon atoms; a thickening agent; and a neutralizer. The second invention (Group II) is restricted to Claims 13-24, drawn to a method of preparing a high alcohol skin sanitizing composition of the Group I Claims.

Applicant hereby affirms the election of Group I, Claims 1-12 and 25, drawn to the composition comprising an aliphatic alcohol, a thickening agent, and a neutralizer. Claims 13-24 are hereby withdrawn and canceled without prejudice or disclaimer and subject to Applicants' right to file a divisional application thereon.

Turning to the rejection of the claims, Claims 1-6 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that the FDA guideline known as "Generally Recognized As Safe" is not a permanent guideline, and therefore, the neutralizer is considered to be a relative term which renders the claim indefinite.

Although the guideline is not permanent, it is publicly available. Accordingly, Claims 1 and 6 have been amended to indicate that the neutralizer used is one designated by the FDA as of February 5, 2002 as a direct food substance that is Generally Regarded As Safe, or as an amino acid permitted for direct addition to food for human consumption. It will be appreciated that February 5, 2002 is the filing date of the subject application. Thus, no new matter has been added to the present invention. Moreover, the guideline is now permanently set inasmuch as those substances that fall under the "Generally Regarded As Safe" FDA guideline as of February 5, 2002 are the neutralizers claimed. Should the Examiner require a copy of the federal guideline in existence on that date, the applicants

can readily supply the same. Accordingly, the rejection of Claims 1-6 as indefinite is now believed to be rendered moot in light of the subject amendments to Claims 1 and 6 set forth herein.

Next, the Examiner has rejected Claims 1-7 and 9-12 under 35 U.S.C. 102(b) as being anticipated by Lins U.S. Patent No. 5,167,950. In particular, the Examiner asserts that Lins teaches a composition having a high alcohol content used as an antiseptic. The patent is said to provide for a high alcohol content, from about 0.1 to 1.5 weight percent of a gelling agent such as a carbomer, and 0.5 to 10 percent of neutralizing agents for the thickening agent such as sodium hydroxide or triethanolamine.

The Applicants have reviewed the cited art, and believe their invention is patentably distinct therefrom. In particular, Applicants note that the Lins patent teaches an aerosol mousse which is dispensed as a foam for use as an antiseptic. Such a foam mousse is extremely porous, unlike the present invention. In other words, the present invention is not a mousse and has a density of at least 0.8 g/ml. These distinctions have been incorporated into Claim 1 of the application. Support for this amendment can be found at page 12, lines 18-21 of the subject specification.

The Examiner, however, has asserted that the same viscosity and density should be possessed by the patented Lins invention because both the patented invention and the instant claimed invention use the very same essential ingredients so that one would have envisioned that both inventions share the same physical properties inherently. However, this is clearly not the case. Although not part of the claimed invention, methods of preparation of the various compositions and additional ingredients added to the composition can and do clearly affect the physical properties of these compositions. In Lins, a foamed mousse is desired. Clearly, such a foamed, porous mousse will not have the same density as the present composition regardless of the amount or the ingredients employed.

The present invention clearly states that it has a density of at least 0.8 g/ml. In comparison, the foam density of mousses typically fall within the range of 0.5 g/ml to 0.2 g/ml. Such a definition is clearly defined and well known to those of ordinary skill in the art as set forth at page 5 of Exhibit A, Guide to Formulating 6% VOC Mousse. In light of the foregoing amendments, it is believed that the present invention is clearly and patentably distinct from the Lins U.S. Patent.

Turning to the next rejection, the Examiner has rejected Claim 25 under 35 U.S.C. 103(a) as being obvious, and therefore, unpatentable over Lins U.S. Patent No. 5,167,950. Unfortunately, the Applicants believe the Examiner has misread Claim 25 of the subject application. Claim 25 requires sodium *hydroxide* as the neutralizer, not sodium *peroxide*. Accordingly, Applicants believe the rejection of Claim 25 is not relevant to the subject claim, and that the amendments as set forth in Claim 1, which have also been provided in Claim 25, renders that claim patentable as well.

The Examiner has also rejected Claim 8 as obvious, and therefore unpatentable, over Lins U.S. Patent No. 5,167,950 in view of B. F. Goodrich Technology Disclosure 1998. While not acquiescing to the Examiner's rejection, the Applicants note that Claim 8 depends from Claim 1 which is believed to be allowable over the cited art. Accordingly, Applicants rely on Claim 8's dependancy for its allowance.

In light of the foregoing, applicants respectfully request the Examiner to reconsider the application and withdraw her rejection of the claims. A Notice of Allowance of Claims 1-10, 12 and 25 is earnestly solicited. Should the Examiner care to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call. No fee is presently believed due.

Respectfully submitted,

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Attorney for Applicants

August 5, 2003

National Starch
PersonalCare

# Guide to Formulating 6% VOC Mousse

**your personal care connection...**
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# Table of Contents

## Introduction

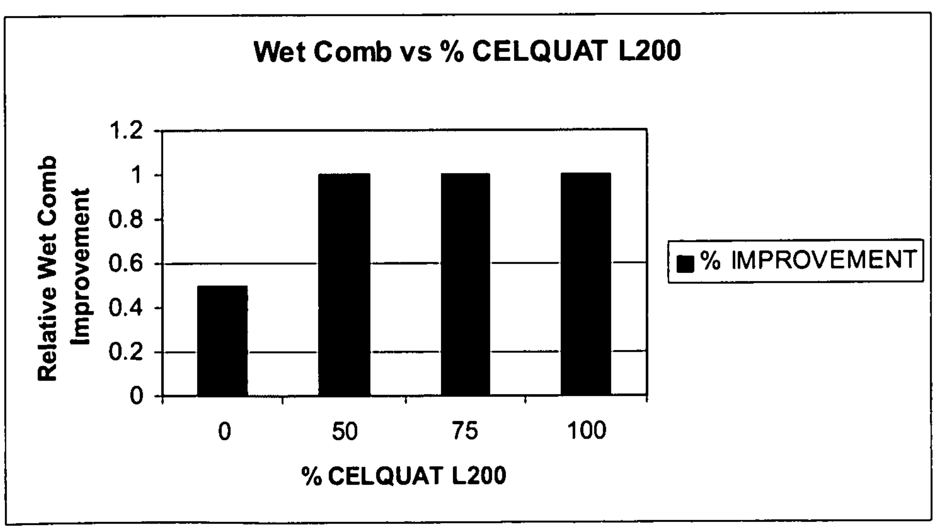
This guide focuses on using the formulation strategies of employing cationic conditioning/styling polymers and blends of cationic and non-ionic conditioning/styling polymers to develop 6% VOC mousse formulas. The guide demonstrates how to select specific polymers, surfactants, and propellants to achieve the foam and on-hair properties you are interested in.

The guide is segmented into three sections. Section 1 details how to select a polymer component of your formula to achieve the on-hair properties you desire. Section 2 presents guides for picking a surfactant and propellant that, in combination with the polymer you've already chosen, will give the basis of a mousse formula with foam properties and on-hair performance you desire. Section 3 is an example of how to use the tools in this guide to create a starting 6% VOC mousse formula.

## Section 1. On-Hair Properties of 6% VOC Mousse

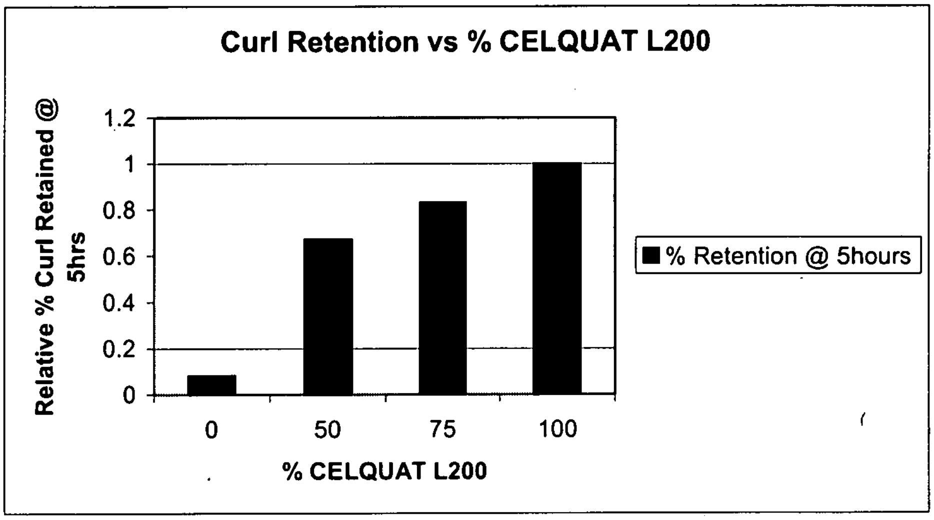
The polymer segment of the 6% VOC Mousse is decisive for controlling the on-hair performance of the mousse product. Consumers have grown to expect excellent wet combability, hold, and static properties from their mousse products. The following data shows how to blend CELQUAT® L-200 and AMAZE™ to achieve mousse formulas with the cost and performance you want for your product. The data is presented as bar graphs of each property compared to the % of CELQUAT L-200 in a blend of CELQUAT L-200 and AMAZE. Therefore, a composition cited on the graph as having 50% CELQUAT L-200 will have a composition, in formula, of 50% CELQUAT L-200 and 50% AMAZE.

### WET COMBABILITY



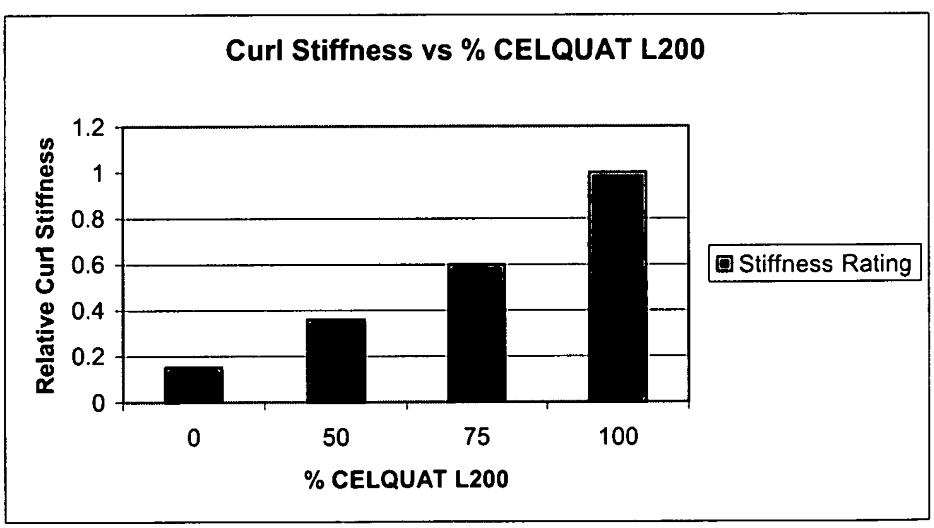
Excellent wet combability improvement is achieved over a broad range of blend ratios.

## CURL RETENTION



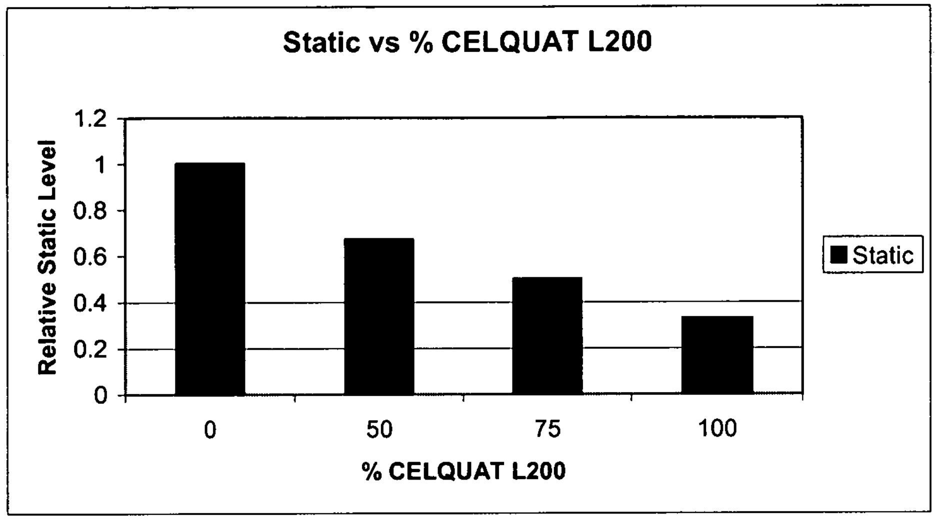

The addition of CELQUAT improves curl retention, thereby improving hold.

## CURL STIFFNESS



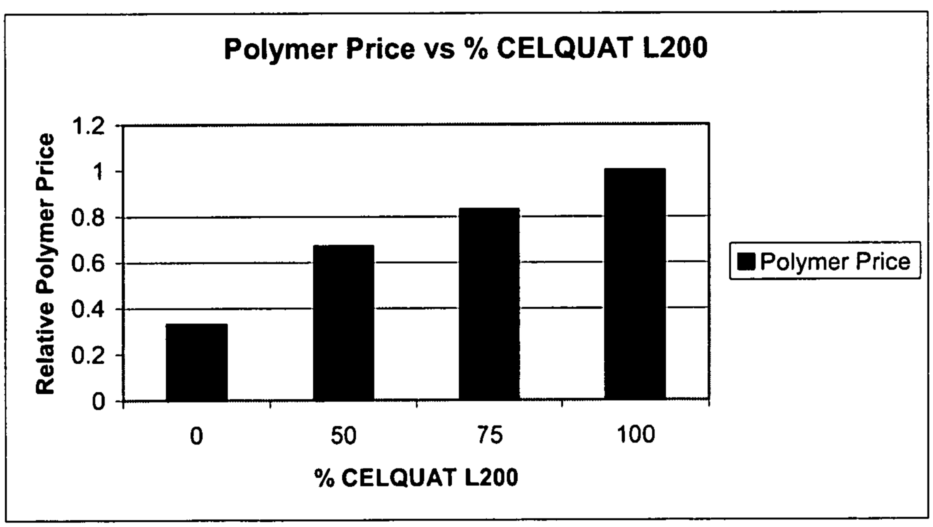
The addition of CELQUAT improves curl stiffness, which results in improved hold.

**STATIC**




The addition of CELQUAT reduces static.

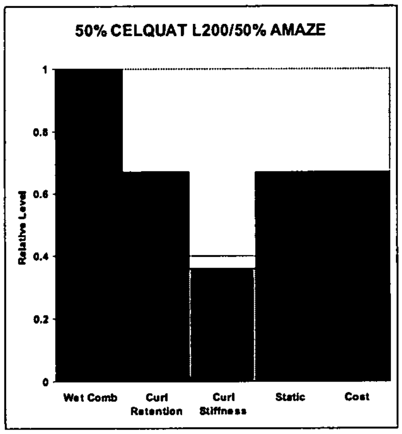
**COST**

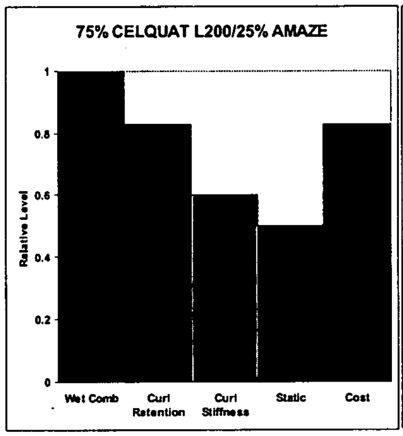


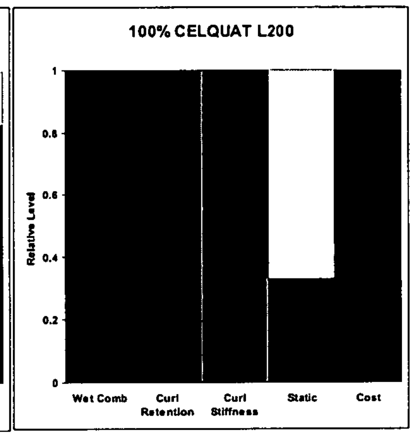

The addition of AMAZE reduces the cost.

## Recommended Polym r Blend Starting Points

Blending CELQUAT L-200 and AMAZE gives you the formulation flexibility to deliver the kinds of properties your customer's seek. We recommend starting your formula at 2% (weight) total polymer with one of the three following ratios of CELQUAT L-200 to AMAZE: 1) 100% CELQUAT L-200, 2) 75% CELQUAT L-200/25% AMAZE, and 3) 50% CELQUAT L-200/50% AMAZE. The plots help you see how the three blends compare to each other on cost and performance.




## Section 2. Foam Properties of 6% VOC Mousse

Foam properties are very important in determining the amount of product dispensed by the consumer and how easily the product can be applied to hair. Foam density, foam bloom rate, and foam strength are all important foam properties and in this section we present data to help you select a starting formula to give you exactly the properties you seek. First, we will look at mousse formulas based entirely on hydrocarbon propellants. Then we will look at mousse formulas based on blends of hydrocarbon and DYMEL 152A.

### Foam Properties Defined

Foam Density is measured by weighing a known volume of fully formed foam. It is reported in the units of grams/milliliter (g/mL). Generally, it is observed that the basic 6% VOC mousse studied by National Starch have foam densities between 0.05g/mL and 0.2g/mL. Details about how foam density varies is captured in the 3D and contour plots of the following sections

Foam Bloom Rate describes the way the foam develops during and after actuation of a mousse product. Foam Bloom Rate is rated on a three point scale but can be viewed

as a continuum from very slow bloom rates to very fast bloom rates. The meaning of the numerical ratings is given below.

| Bloom Rate Rating | Observed Behavior |
|---|---|
| 1 | Product dispenses as a fully formed foam. Very fast bloom rate. Commercial product example: Salon Selectives |
| 2 | Product dispenses as a partially formed foam and the foam continues to grow after actuation. Moderate bloom rate. Commercial product example: Pantene |
| 3 | Product dispenses as a thin liquid and the foam grows slowly after product actuation. Very slow bloom rate. Commercial product example: Paul Mitchell |

Foam Strength describes the way the foam breaks down when it is mechanically manipulated. Foam Strength is rated on a five point scale but can be viewed as a continuum from very weak foams to very strong foams. The meaning of the numerical ratings is given below.

| Foam Strength Rating | Observed Behavior |
|---|---|
| 1 | Foam completely collapses when touched. No commercial product examples |
| 3 | Foam splits open when touched and remaining untouched foam stays in tact. Commercial product example: Pantene |
| 5 | Foam does not break down when touched three times. Commercial product example: Paul Mitchell |

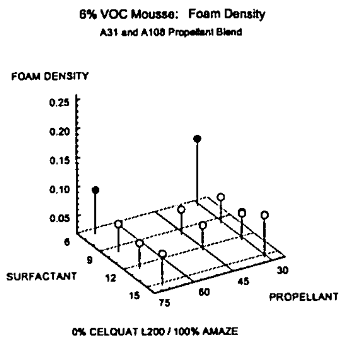
**Section 2A. Hydrocarbon Blends**

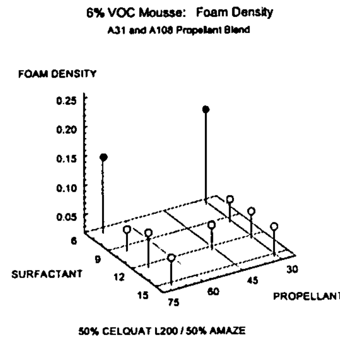
Blending n-butane (Propellant A-31) and propane (Propellant A-108) can achieve a wide range of different pressures at attractive costs. Generally, the pressure should be kept below 70psi in order to be under the strength limits of commonly used containers for aerosol mousse products. The pressures cited in the following figures are the pressures of pure propellant blends according to published pressure tables. Actual pressures of mousse containing these blends may not be the same.

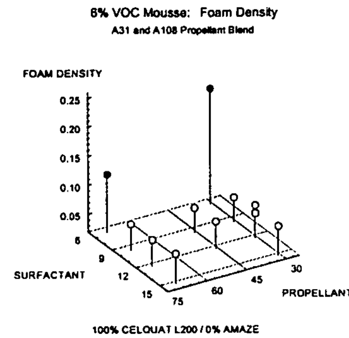
**Foam Density in Hydrocarbon Blends**

Foam density of mousse based on hydrocarbon blends depends on polymer (% of CELQUAT L-200 in a blend of CELQUAT L-200 and AMAZE), Surfactant HLB, and Propellant Pressure. The data is not easily fit by a model that gives meaningful predictions. Therefore, the foam density data for a very broad range of compositions is

provided here in the form of three-dimensional graphs. Simply locate the graph for the specific polymer blend ratio of interest and then select a Surfactant HLB and Propellant Pressure to give you the desired density. For those cases where the data is not available for the specific blend ratio you are interested in, simply use the one that is closest as an approximation.

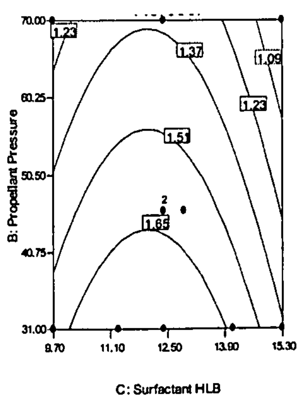


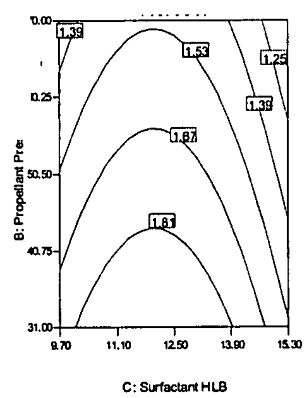



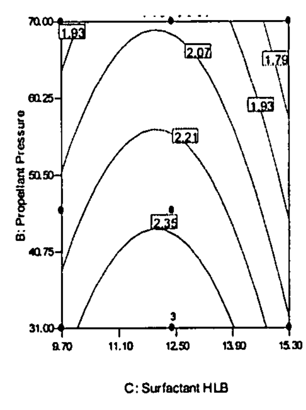



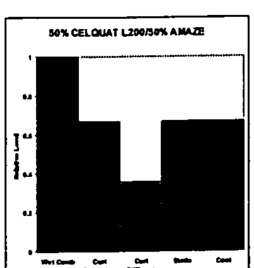

## Foam Bloom Rate in Hydrocarbon Blends

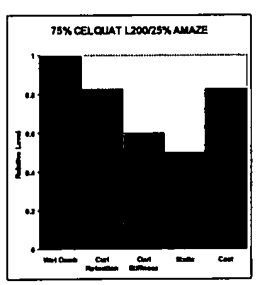
The foam bloom rate of mousse, based on hydrocarbon blends, depends very strongly on propellant pressure and polymer. The following three contour plots show how to control the foam bloom rate for the three recommended polymer blends. For convenience, we've reproduced the relative properties of the three recommended blends along with the contour plots.

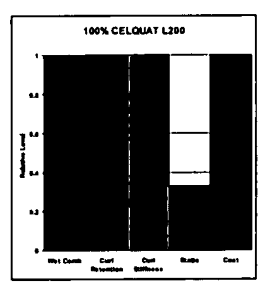


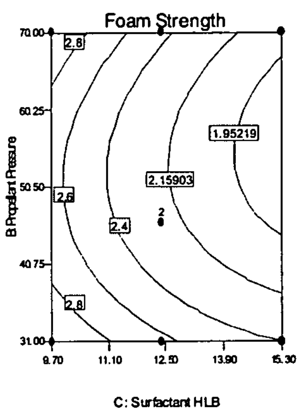



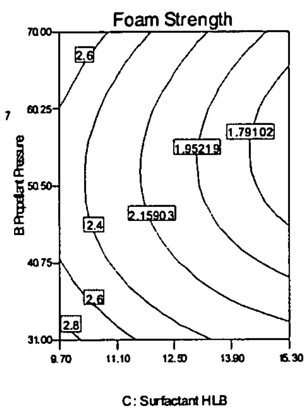



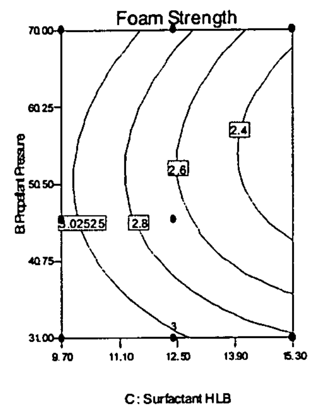



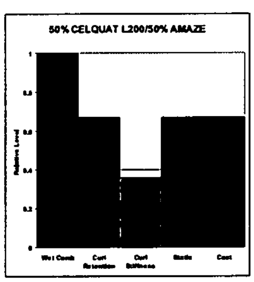
## Foam Strength in Hydrocarbon Blends

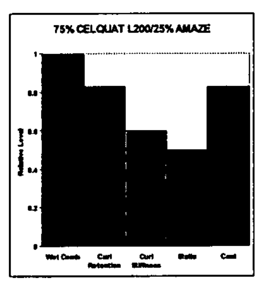
Foam strength depends very strongly on the polymer. The following three contour plots show how to control foam strength for the three recommended polymer blends. For convenience we've reproduced the relative properties of these three recommended blends along with the contour plots.

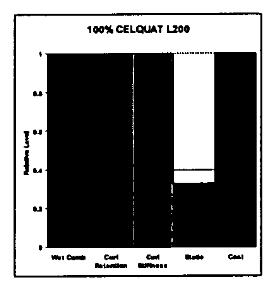


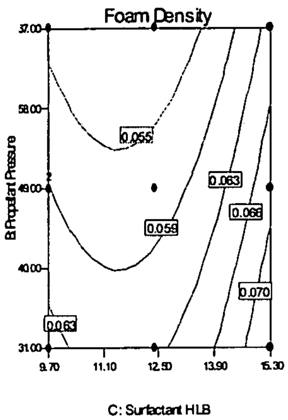



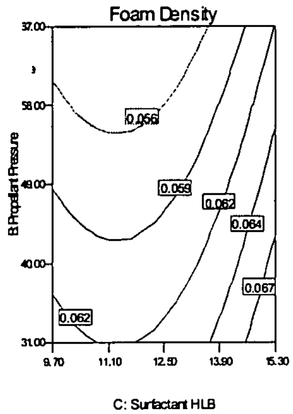

## Section 2B. Hydrocarbon/DYMEL 152A Blends

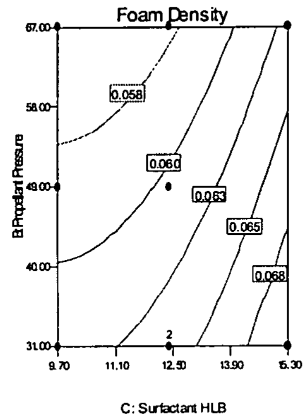
Blending n-butane (Propellant A-31) and DYMEL 152A can achieve a wide range of different pressures. However, doing so allows the formulator to add more propellant due to DYMEL 152A's non-VOC status. Generally, the pressure should be kept below 70psi in order to be under the strength limits of commonly used containers for aerosol mousse products. The pressures cited in the following figures are the pressures of pure propellant blends according to published pressure tables. Actual pressures of mousse containing these blends may not be the same.

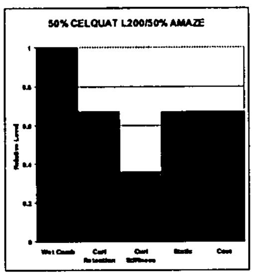
## Foam Density in Hydrocarbon/DYMEL 152A Blends

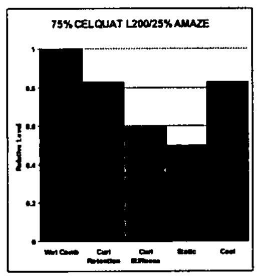
Foam density of mousse based on hydrocarbon/ DYMEL 152A blends depends very strongly on polymer (% of CELQUAT L-200 in a blend of CELQUAT L-200 and AMAZE). The foam density data here can be modeled very successfully. The following three contour plots show how to control foam density for the three recommended polymer blends. For convenience we've reproduced the relative properties of these three recommended blends along with the contour plots.

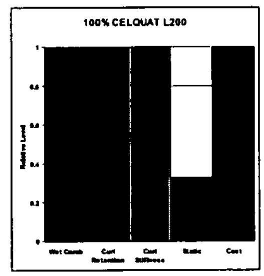


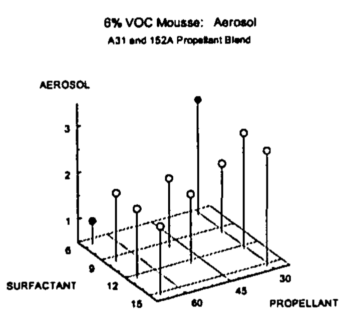



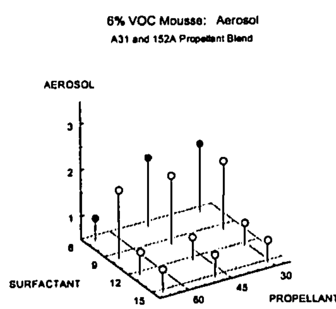




## Foam Bloom Rate in Hydrocarbon/DYMEL 152A Blends

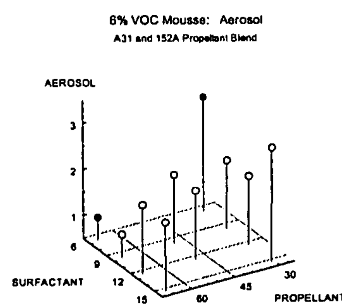
Foam bloom rate of mousse based on hydrocarbon/DYMEL 152A blends depends on: polymer (% of CELQUAT L-200 in a blend of CELQUAT L-200 and AMAZE), Surfactant HLB, and Propellant Pressure. The data is not easily fit by a model that gives meaningful predictions. Therefore, the foam bloom rate data for a very broad range of compositions is provided here in the form of three dimensional graphs. Simply locate the graph for the specific polymer blend ratio of interest and then select a Surfactant HLB and Propellant Pressure to give you the desired bloom rate.



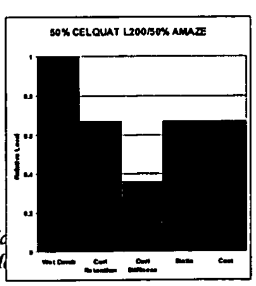

0% CELQUAT L200 / 100% AMAZE

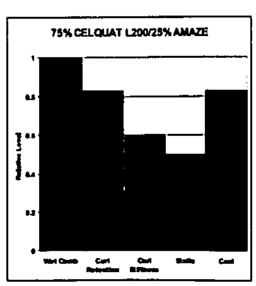


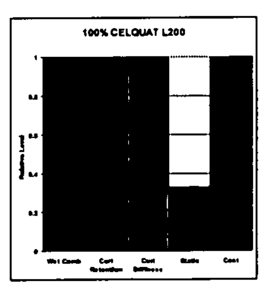

50% CELQUAT L200 / 50% AMAZE




100% CELQUAT L200 / 0% AMAZE

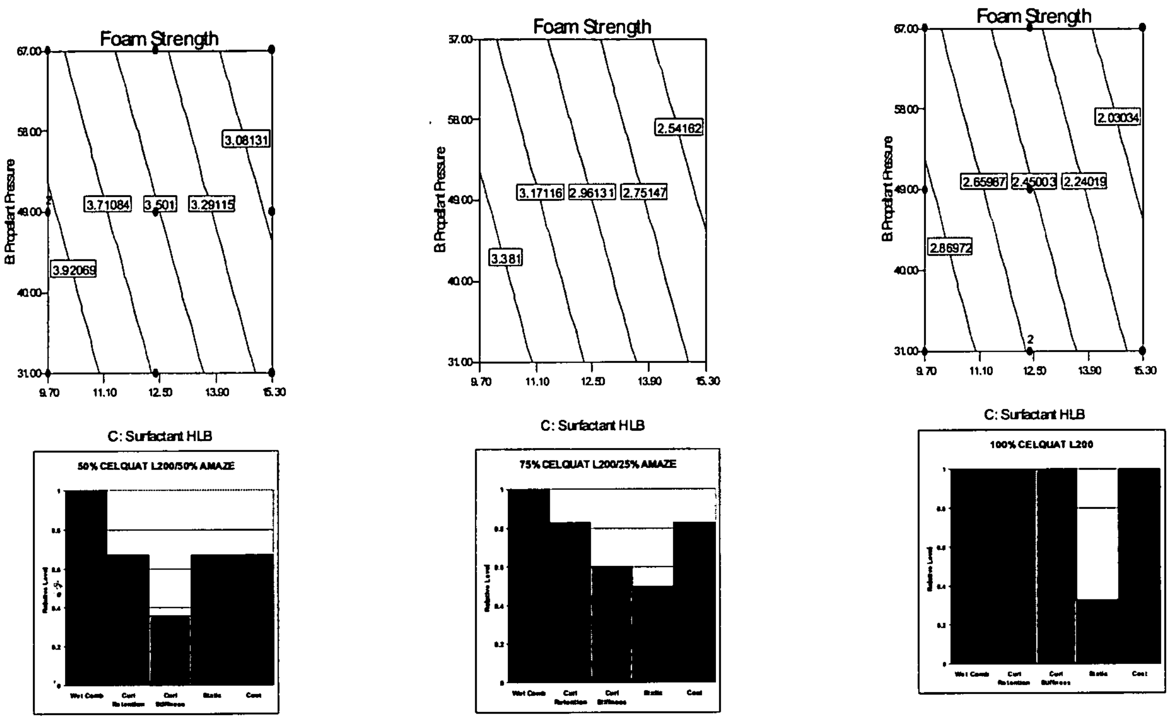


## Foam Strength in Hydrocarbon/DYMEL 152A Blends

Foam strength depends very strongly on the polymer. The following three contour plots show how to control foam strength for the three recommended polymer blends. For convenience we've reproduced the relative properties of these three recommended blends along with the contour plots.




## Section 3. Example: Creating A Starting Formula Using Hydrocarbon Blends

Our target is a 6% VOC mousse product that has excellent curl retention, moderate stiffness, excellent wet combability, and low static. The foam should have a moderate bloom rate, a foam density less than 0.06g/mL, and should break down easily when handled. The formulation cost should be as low as possible.

Considering the on-hair attributes of importance, the 75% CELQUAT L-200 and 25% AMAZE blend shows a very good balance of curl retention, stiffness, wet combability, static, and cost.

According to the table in Section 2 foam with a moderate bloom rate would have a numerical bloom rate of about 1.5-2.5. Foam that breaks down easily when handled would have a numerical foam strength of 2-4.

First, we can use the data for a 50% CELQUAT L-200/50% AMAZE blend as an approximation for foam density. The 3D plot (below) shows us that we can achieve the

foam density requirement (0.06g/mL) with all possible formulas EXCEPT those with Surfactant HLB = 6.7.

The 3D plot teaches us that target foam densities can be achieved with surfactants having HLB > 6.7 and propellant pressures over a very broad range.

Second, we can use the contour plots for foam strength and foam bloom rate for 75% CELQUAT L-200/25% AMAZE blend to determine what Surfactant HLB and Propellant Pressure to choose.

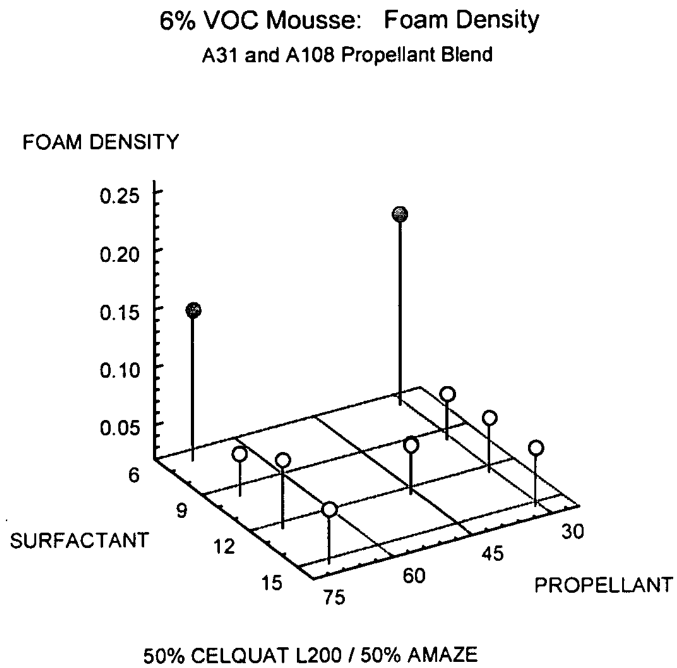
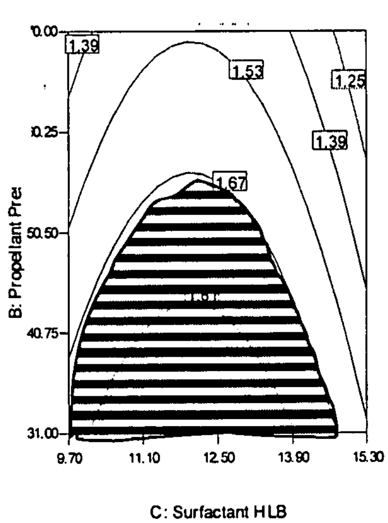
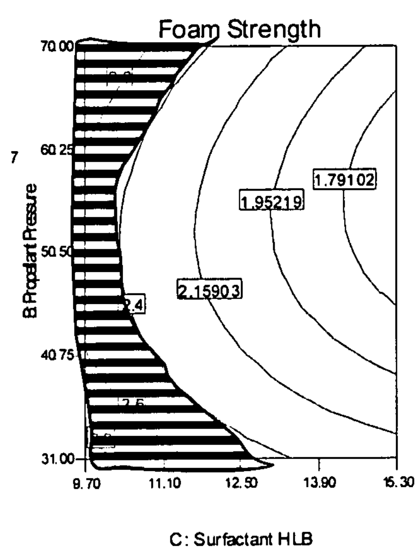


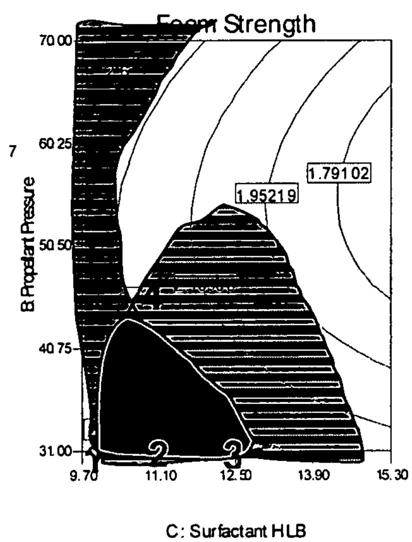

Figure 1. Foam Density for 50/50 CELQUAT L-200/AMAZE Blend: Useful data to approximate the foam density for our target formulation.



A bloom rate greater than 1.5 can be achieved with formulas having a Surfactant HLB between 11 and 15.3 as long as the Propellant Pressure is less than approximately 55psi (red-shaded area on bloom rate contour plot). A foam strength greater than 2.5 can be achieved to left of the contour line labeled 2.4 in the foam strength plot. The two compositional areas are overlaid on the plot below and the compositional area of intersection is shaded in green.

We recommend preparing 4 experiments that are evenly spaced throughout the compositional space of interest predicted by the models. As an example, 4 compositions are marked on the predicted area of interest in the model below with numbers.




These four samples systematically vary surfactant HLB and propellant pressure throughout the area of interest predicted by the model. Sample #4 is optional because it is outside of the predicted area but included here because it adds completeness to the experiment.

| | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| **Surfactant HLB** | 9.7 | 11.3 | 12.5 | 11.3 |
| **Propellant Pressure** | 31 | 46 | 40 | 31 |

These models were created using ethoxylated alcohol surfactants. We, therefore, suggest that only these types of surfactants be employed in your starting formulations. We highly recommend the following three surfactants be available during your mousse formulations activities.

| Trade Name | INCI Name | HLB |
|---|---|---|
| Brij 30 | Laureth-4 | 9.7 |
| Brij 56 | Ceteth-10 | 12.9 |
| Brij 78 | Steareth-20 | 15.3 |

Using these surfactants, a blend ratio of CELQUAT L-200 and AMAZE of 3:1, and propellants A-31, A-46, and A-108 we can translate the recommendations of the models into the following formulations.

| | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| **CELQUAT L-200** | 1.5 | 1.5 | 1.5 | 1.5 |
| **AMAZE** | 0.5 | 0.5 | 0.5 | 0.5 |
| **Brij 30** | 0.5* | 0.25* | -- | 0.25 |
| **Brij 56** | -- | 0.25* | 0.5 | 0.25 |
| **Propellant A-31** | 6 | -- | 5.45 | 6 |
| **Propellant A-46** | -- | 6 | -- | -- |
| **Propellant A-108** | -- | -- | 0.55 | -- |
| **Water** | 91.5 | 91.5 | 91.5 | 91.5 |
| | | | | |

*Note: Blending Brij 30 and Brij 56 at a ratio of 1:1 gives a blended HLB of 11.3.

The foam characteristics of these four compositions are summarized in the table below.

| | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| **Foam Density** | 0.065g/mL | 0.058g/mL | 0.058g/mL | 0.057g/mL |
| **Foam Strength** | 3 | 3 | 3 | 3 |
| **Foam Bloom Rate** | 2 | 2 | 2 | 2 |

All four basic mousse formulas show foam strength and bloom rate characteristics that match the requirements. Sample #1 must be eliminated because it has a foam density higher than the requirement.

Therefore, any (or all) of the three remaining samples can be evaluated for on-hair properties and further customized to fulfill your specific product objectives.